

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RECEIVED

## In Re Application of:

Ayyavoo et al.

Serial No.: 09/486,625

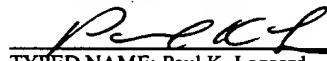
Group Art Unit: 1643

Filing Date: September 13, 2000

Examiner: Unknown

For: ATTENUATED VIF DNA IMMUNIZATION  
CASSETTES FOR GENETIC VACCINESDATE OF DEPOSIT: 18 JANUARY 2001

I HEREBY CERTIFY THAT THIS PAPER IS BEING  
DEPOSITED WITH THE UNITED STATES POSTAL  
SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID  
ON THE DATE INDICATED ABOVE AND IS ADDRESSED  
TO THE ASSISTANT COMMISSIONER FOR PATENTS,  
WASHINGTON, DC 20231.

  
\_\_\_\_\_  
TYPED NAME: Paul K. Legaard  
REGISTRATION NO.: 38,534

Assistant Commissioner for Patents  
Washington DC 20231

Dear Sir:

**INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

- In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, before the mailing date of a first Office Action on the merits of the above-identified application, no additional fee is required, or before the mailing date of a first office action after the filing of request for continued examination under §1.114.

- In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with  the first or  second After Final Submission, therefore:
  - Certification in Accordance with §1.97(e) is attached; or
  - The fee of \$180.00 as set forth in §1.17(p) is attached.
- In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or before an action that otherwise closes prosecution in the application, therefore:
  - Certification in Accordance with §1.97(e) is attached; or
  - The fee of \$180.00 as set forth in §1.17(p) is attached.
- In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with §1.97(e); and the submission fee of \$180.00 as set forth in §1.17(p).
- Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.
- Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:
  - In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
  - In accordance with §1.98(d), copies of the following references listed on the attached Form PTO-1449 are not enclosed herewith because they were

previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. §120 have been made in the instant application:

- Copies of references [list as appropriate] listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior application Serial No. , filed .
- If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050.  
This form is submitted in duplicate.

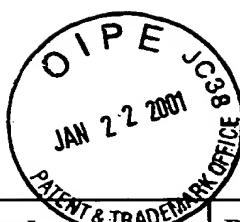
The relevance of those listed references which are not in the English language is as follows:

There are no listed references which are not in the English language.

Date: 18 JANUARY 2001

  
\_\_\_\_\_  
Paul K. Legaard  
Registration No. 38,534

WOODCOCK WASHBURN KURTZ  
MACKIEWICZ & NORRIS LLP  
One Liberty Place - 46th Floor  
Philadelphia, PA 19103  
Telephone: (215) 568-3100  
Facsimile: (215) 568-3439



<b>Form PTO-1449 Modified</b>		Docket No. <b>UPAP-0287</b>	Serial No. <b>09/486,625</b>
List of Patent and Publications Cited by Applicant		Applicant <b>Ayyavoo et al.</b>	
U.S. Department of Commerce Patent and Trademark Office		Filing Date <b>September 13, 2000</b>	Group <b>1643</b>
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	AA	Aldrovandi, et al., "Replication and Pathogenicity of Human Immunodeficiency Virus Type 1 Accessory Gene Mutants in SCID-hu Mice", <i>J. Virology</i> , 1996, Vol. 70, No. 3, pp. 1505-1511	
	AB	Ameisen, et al., "Antibody Response to the HIV-1 Regulatory GEI Products NEF, VIF, and VPR in HIV-1 Infectious Seronegative Individuals," <i>Int Conf. AIDS</i> , 1989, Vol. 5, Page 533	
	AC	Ayyavoo, et al., "Analysis of Genetic Heterogeneity, Antigenicity, and Biological Characteristics of HIV-1 in a Maternal Transmitter and Nontransmitter Patient Pair," <i>DNA and Cell Biology</i> , 1996, Vol. 15, No. 7, pp. 571-580	
	AD	Arya et al., "Three Novel Genes of Human T-lymphotropic Virus Type III: Immune Reactivity of their Products with Sera from Acquired Immune Deficiency Syndrome Patients," <i>Proc. Natl. Acad. Sci. USA</i> , 1986, Vol. 83, pp. 2209-2213	
	AE	Blanc et al., "Transcomplementation of VIF- HIV-1 Mutants in CEM Cells Suggests That VIF Affects Late Steps of the Viral Life Cycle," <i>Virology</i> , 1993, Vol. 193, pp. 186-192	
	AF	Borman et al., "Human Immunodeficiency Virus Type 1 Vif- Mutant Particles from Restrictive Cells: Role of Vif in Correct Particle Assembly and Infectivity," <i>J. Virol</i> , 1995, Vol. 69, No. 4, pp. 2058-2067	
	AG	Cullen et al., "Regulatory Pathways Governing HIV-1 Replication," <i>Cell</i> , 1989, Vol. 58, pp. 423-426	
	AH	Desrosiers, "HIV with Multiple Gene Deletions as a Live Attenuated Vaccine for AIDS," <i>AIDS Res. And Human Retroviruses</i> , 1992, Vol. 8, No. 3, pp. 411-421	
	AI	Dougherty et al., "Determination of the Rate of Base-Pair Substitution and Insertion Mutations in Retrovirus Replication," <i>J. Virol</i> , 1988, Vol. 62, No. 8, pp. 2817-2822	
	AJ	Fisher et al., "Biologically Diverse Molecular Variants Within a Single Hiv-1 Isolate," <i>Nature</i> , 1988, Vol. 334, pp. 444-447	
	AK	Fynan et al., "Dna Vaccines: Protective Immunization by Parenteral, Mucosal, and Gene-gun Inoculations," <i>Proc. Natl. Acad. Sci. USA</i> , 1993, Vol. 90, pp. 11478-11482	
	AL	Gabuzda et al., "Role of vif in Replication of Human Immunodeficiency Virus Type 1 in CD4+ T Lymphocytes," <i>J. Virol</i> , 1992, Vol. 66, No. 11, pp. 6489-6495	
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>	

**Form PTO-1449 Modified**

Docket No.  
**UPAP-0287**

Serial No.  
**09/486,625**

**List of Patent and Publications  
Cited by Applicant**

Applicant  
**Ayyavoo et al.**

U.S. Department of Commerce  
Patent and Trademark Office

Filing Date  
**September 13, 2000**

Group  
**1643**

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

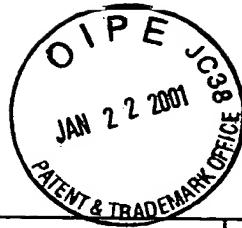
	AM	Garrett et al., "Rev Activates Expression of the Human Immunodeficiency Virus Type 1 <i>vif</i> and <i>vpr</i> Gene Products," <i>J. Virol.</i> , 1992, Vol. 65, No. 3, pp. 1653-1657
	AN	Gibbs et al., "Construction and <i>In Vitro</i> Properties of HIV-1 Mutants with Deletions in "Nonessential" Genes," <i>Aids Res. And Human Retroviruses</i> , 1994, Vol. 10, No. 4, pp. 343-350
	AO	Goncalves et al., "Subcellular Localization of the Vif Protein of Human Immunodeficiency Virus Type 1," <i>J. Virol.</i> , 1994, Vol. 68, No. 2, pp. 704-712
	AP	Guy et al., "A Specific Inhibitor of Cysteine Proteases Impairs a Vif-Dependent Modification of Human Immunodeficiency Virus Type 1 Env Protein," <i>J. Virol.</i> , 1991, Vol. 65, No. 3, pp. 1325-1331
	AQ	Hevey et al., "Complementation of Human Immunodeficiency Virus Type 1 <i>vif</i> Mutants in Some CD4+ T-Cell Lines," <i>Virus Res.</i> , 1994, Vol. 33, pp. 269-280
	AR	Kan et al., "Identification of HTLV-III/LAV <i>sor</i> Gene Product and Detection of Antibodies in Human Sera," <i>Science</i> , 1986, Vol. 231, pp. 1553-1555
	AS	Lamhamedi et al., "Qualitative and Quantitative Analysis of Human Cytotoxic T-lymphocyte Responses to HIV-1 Proteins," <i>AIDS</i> , 1992, Vol. 6, No. 11, pp. 1249-1258
	AT	Ma et al., "Cysteine Residues in the Vif Protein of Human Immunodeficiency Virus Type 1 Are Essential for Viral Infectivity," <i>J. Virol.</i> , 1994, Vol. 68, No. 3, pp. 1714-1720
	AU	Mahalingam et al., "The Carboxy-Terminal Domain is Essential for Stability and Not for Virion Incorporation of HIV-1 Vpr into Virus Particles," <i>Virol.</i> , 1995, Vol. 214, pp. 647-652
	AV	Meyerhans et al., "Temporal Fluctuations in HIV Quasispecies in Vivo Are Not Reflected by Sequential HIV Isolations," <i>Cell</i> , 1989, Vol. 58, pp. 901-910
	AW	Michael et al., "Defective Accessory Genes in a Human Immunodeficiency Virus Type 1-Infected Long-Term Survivor Lacking Recoverable Virus," <i>J. Virol.</i> , 1995, Vol. 69, No. 7, pp. 4228-4236
	AX	Nagashunmugam et al., "Cell-Free HIV-1 <sub>Zr6</sub> <i>vif</i> Mutants Are Defective in Binding to Peripheral Blood Mononuclear Cells and in Internalization," <i>DNA Cell Biol.</i> , 1996, Vol. 15, No. 5, pp. 353-361

EXAMINER

DATE CONSIDERED



<b>Form PTO-1449 Modified</b>		Docket No. <b>UPAP-0287</b>	Serial No. <b>09/486,625</b>
List of Patent and Publications Cited by Applicant		Applicant <b>Ayyavoo et al.</b>	
U.S. Department of Commerce Patent and Trademark Office		Filing Date <b>September 13, 2000</b>	Group <b>1643</b>
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	AY	Oberste et al., "Conservation of Amino Acid Sequence Motifs in Lentivirus Vif Proteins," <i>Virus Genes</i> , 1992, Vol. 6, No. 1, pp. 95-102	
	AZ	Pircher et al., "Viral Escape by Selection of Cytotoxic T Cell-Resistant Virus Variants <i>In Vivo</i> ," <i>Nature</i> , 1985, Vol. 346, pp. 629-633	
	BA	Ratner et al., "Complete Nucleotide Sequence of the AIDS Virus, HTLV-III," <i>Nature</i> , 1985, Vol. 313, pp. 277-284	
	BB	Sakai et al., "Cell Dependent Requirement of Human Immunodeficiency Virus Type 1 Vif Protein for Maturation of Virus Particles," <i>J. Virol</i> , 1993, Vol. 67, No. 3, pp. 1663-1666	
	BC	Schwartz et al., "Expression of Human Immunodeficiency Virus Type 1 vif and vpr mRNAs Is Rev-dependent and Regulated by Splicing," <i>Virol</i> , 1991, Vol. 183, pp. 677-686	
	BD	Schwander et al., "Prevalance of Antibodies to Recombinant Virion Infectivity Factor in the Sera of Prospectively Studied Patients with HIV-1 Infection," <i>J. of Medical Virol</i> , 1992, Vol. 36, pp. 142-146	
	BE	Shackett et al., "Analysis of the vif Gene of Feline Immunodeficiency Virus," <i>Virol</i> , 1994, Vol. 204, pp. 860-867	
	BF	Sodroski et al., "Replicative and Cytopathis Potential of HTLV-III/LAV with sor Gene Deletions," <i>Science</i> , 1986, Vol. 231, pp. 1549-1553	
	BG	Sova et al., "Conservation of an Intact Human immunodeficiency Virus Type-1 vif gene In Vitro and In Vivo," <i>J. Virol</i> , 1995, Vol. 69, No. 4, pp. 2557	
	BH	Srinivasan et al., "Molecular Characterization of Human Immunodeficiency Virus from Zaire: Nucleotide Sequence Analysis Identifies Conserved and Variable Domains in the Envelope Gene," <i>Gene</i> , 1987, Vol. 52, pp. 71-82	
	BI	Tang et al., "Genetic Immunization is a Simple Method for Eliciting an Immune Response," <i>Nature</i> , 1992, Vol. 356, pp. 152-154	
	BJ	Trono., " HIV Accessory Proteins: Leading Roles for the Supporting Cast," <i>Cell</i> , 1995, Vol. 82, pp. 189-192	
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>	



<b>Form PTO-1449 Modified</b>			Docket No. <b>UPAP-0287</b>	Serial No. <b>09/486,625</b>
List of Patent and Publications Cited by Applicant			Applicant <b>Ayyavoo et al.</b>	
U.S. Department of Commerce Patent and Trademark Office			Filing Date <b>September 13, 2000</b>	Group <b>1643</b>
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>				
	BK	Ulmer et al., " Heterologous Protection Against Influenza by injection of DNA Encoding a Viral Protein," <i>Science</i> , 1993, Vol. 259, pp. 1745-1749		
	BL	Volsky et al., " the Human Immunodeficiency Virus Type 1 <i>vif</i> Gene: The Road from an Accessory to an Essential Role in Human Immunodeficiency Virus Type 1 Replication," <i>Curr. Topics Micro. Immunol.</i> , 1995, Vol. 193, pp. 157-168		
	BM	von Schwedler et al., "vif Is Crucial for Human Immunodeficiency Virus Type 1 Proviral DNA Synthesis in Infected Cells," <i>J. Virol.</i> , 1993, Vol. 67, No. 8, pp. 4945-4955		
	BN	Wang et al., " Gene Inoculation Generates Immune Responses Against Human Immunodeficiency Virus Type 1," <i>Proc. Natl. Acad. Sci. USA</i> , 1993, Vol. 90, pp. 4156-4160		
	BO	Wang et al., "DNA Inoculation Induces Neutralizing Immune Responses Aganist Human Immunodeficiency Virus Type 1 in Mice and Nonhuman Primates," <i>DNA And Cell Biol.</i> , 1993, Vol. 12, No. 9, pp. 799-805		
	BP	Wang et al., " Nucleic acid-based Immunization Aganist HIV-1 Induction of Protective <i>in vivo</i> Immune Responses," <i>AIDS</i> , 1995, Vol. 9 (Suppl. A), pp. S159-S170		
	BQ	Wolfs et al., "Naturally Occurring Mutations within HIV-1 V3 Genomic RNA Lead to Antigenic Variation Dependent on a Single Amino Acid Substitution," <i>Virol.</i> , 1991, Vol. 185, pp. 195-205		
	BR	Wieland et al., " In Vivo Genetic Variability of the HIV-1 <i>vif</i> Gene," <i>Virol.</i> , 1994, Vol. 203, pp. 43-51		
	BS	Wieland et al., "Antigenic Domains of the HIV-1 <i>vif</i> Protein as Recognized by Human Seras and Murine Monoclonal Antibodies," <i>AIDS Res. Human. Retrovir.</i> , 1991, Vol. 7, No. 11, pp. 861-867		
	BT	Yang et al., "Phosphorylation of Vif and Its Role in HIV-1 Replication," <i>J. Biol. Chem.</i> , 1996, Vol. 271, No. 17, pp. 10121-10129		
<b>EXAMINER</b>			<b>DATE CONSIDERED</b>	



Sheet 5 of 5

**Form PTO-1449 Modified**

## List of Patent and Publications Cited by Applicant

**U.S. Department of Commerce  
Patent and Trademark Office**

Docket No.  
**UPAP-0287**

Serial No.  
09/486,625

**Applicant**  
**Ayyavoo et al.**

Filing Date  
**September 13, 2000**

**RECEIVED**

JAN 24 2001

## **U. S. PATENT DOCUMENTS**

## **FOREIGN PATENT DOCUMENTS**

Examiner Initial		Document No.	Date	Country	Translation	
					YES	NO
	BY	WO 90/11092	10/04/90	PCT		
	BZ	WO 93/17706	09/16/93	PCT		
	CA	WO 93/23552	11/25/93	PCT		
	CB	WO 94/16737	08/04/94	PCT		

**EXAMINER**

**DATE CONSIDERED**